DEPARTMENT OF HEALTH AND HUMAN SERVICE

Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127

Telephone: 504-253-4519
Facsimile: 504-253-4520

May 9, 2002

WARNING LETTER NO. 2002-NOL-29

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Walter D. Norris, President
Pride of the South Catfish, Inc.
Highway 388, HCO-1 Box 2
Brooksville, Mississippi 39739

Dear Mr. Norris:

We inspected your firm, located at Highway 388, HCO-1, Box 2, Brooksville, Mississippi, on November 29 - 30, 2001, and found that you have serious deviations from seafood Hazard Analysis Critical Control Point (HACCP) regulations, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123), and the Current Good Manufacturing Practice (CGMP) regulations in manufacturing, packing, or holding food for human consumption, 21 CFR 110. These deviations cause your catfish products to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and the seafood HACCP regulations through links in FDA's home page at http://www.fda.gov.

The deviations were as follows:

- You must have a HACCP plan that lists the food safety hazards that are reasonably likely to occur to comply with 21 CFR 123.6(c)(1). However, your firm's HACCP plan for fully cooked, breaded catfish patties does not list the food safety hazards of pathogen survival during the cooking operation, and undeclared allergens such as wheat flour and soy protein.

- You must adequately monitor sanitation conditions and practices during processing to comply with 21 CFR 123.11(b)(4) & (5). However, your firm does not perform daily monitoring of the hand washing/sanitizing facilities and monitoring of the food packaging material from adulteration.

We may take action without further notice if you do not promptly correct these violations. For instance, we may seize your product(s) and/or enjoin your firm from operating. We are aware that during our inspection you made a verbal commitment to correct violations observed at your firm. However, you must respond in writing, within three (3) weeks from your receipt of this letter, outlining specific actions you have taken to correct the deficiencies and to assure that such violations will not recur. You may wish to include in your response documentation such as your

revised HACCP plans or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect you will explain the reason for the delay and give us a date by which you will correct any remaining deficiencies.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the seafood HACCP regulations, and the CGMP regulations. You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Mark W. Rivero, Compliance Officer, at the address above. If you have questions regarding any issue in this letter, please contact Mr. Rivero at (504) 253-4519.

Sincerely,

Carl E. Draper
District Director
New Orleans District

Enclosure: FDA Form 483